Attorney's Docket No. 1003300-000794

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	
Johan Wanselin et al.	Group Art Unit: 1744
Application No.: 09/879,117	Examiner: MONZER R CHORBAJI
Filed: June 13, 2001	Appeal No.: _____
For: DEVICE FOR AN AUTOCLAVE	

APPEAL BRIEF

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APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This appeal is from the decision of the Primary Examiner dated December 14, 2006 finally rejecting claims 1-20, which are reproduced as the Claims Appendix of this brief.

☐ A check covering the ☐ $ 250 ☐ $ 500 Government fee is filed herewith.

☒ Charge ☐ $ 250 ☒ $ 500 to Credit Card. Form PTO-2038 is attached.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

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I. Real Party in Interest

The present application is assigned to Getings Skärhamn AB. Getings Skärhamn AB is the real party in interest, and is the assignee of Application No. 09/879,117.

II. Related Appeals and Interferences

The Appellant legal representative, or assignee, does not know of any other appeal or interferences which will affect or be directly affected by or have bearing on the Board's decision in the pending appeal.

III. Status of Claims

This application contains claims 1-20, all of which are pending and stand finally rejected. Claims 1 and 11-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Huston et al.* (U.S. Patent No. 3,407,027) in view of *Hennebert et al.* (U.S. Patent No. 4,764,351). Claims 2, 5, 6 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Huston et al.* '027 in view of *Hennebert et al.* '351 and further in view of *Spence* (U.S. Patent No. 4,919,888). Claims 3, 4, 7-9 and 16-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Huston et al.* '027 in view of *Hennebert et al.*'351 and *Spence* '888 and further in view of *Quehl* (U.S. Patent No. 4,165,404). Claim 10 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Huston et al.* '027 in view of *Hennebert et al.* '351, *Spence* '888 and *Quehl* '404 and further in view of *Leimbacher et al.* (U.S. Patent No. 5,837,181). Claim 20 is rejected under 35 U.S.C. § 103(a) as

being unpatentable over *Huston et al.* '027 in view of *Hennebert et al.* '351, and further in view of *Houston et al.* (U.S. Patent No. 5,894,014).

This appeal is directed to claims 1-20.

IV. Status of Amendments

The amendments made in the Amendment filed on September 28, 2006 were entered. There were no claim amendments submitted subsequent to the final Office Action of December 14, 2006.

V. Summary Claimed Subject Matter

Referring to Figure 1, Claim 1 is directed to a sterilisation chamber (3) for use in an autoclave device (1) including a housing (2), pressure means, and display means (4). Page 5, lines 6-14. The sterilisation chamber comprises a front planar wall surface (3b) including a front opening for allowing access to said chamber, a rear planar wall surface (3b), and a chamber body portion (3a) disposed therebetween. Page 5, lines 15-19; The sterilisation chamber (3) is adapted to enclose goods to be sterilized during a sterilisation process. The sterilisation chamber (3) is releasably fastened within the autoclave device (1) by releasably connecting the front wall surface (3b) and the rear wall surface (3b) directly to the housing (2) of the autoclave device. Page 6, lines 24-32. The sterilisation chamber (3) comprises at least an inlet (3d) integrally formed with said chamber for releasable connection to a sterilant source from the autoclave device. Page 7, lines 3-10. Further, an interior of said sterilisation chamber is pressurized during the autoclave process so as to define a sealed pressure chamber. Page 7, lines 14-17. The sterilisation chamber (3) defines a self supported structure manufactured essentially

from a polymeric material having natural heat isolating properties so as to reduce the risk of burning to a person touching the housing of the autoclave device. Page 5, line 33 - Page 6, line 5.

The above comparison of the claimed subject matter to the specification and drawings is not meant to limit the recited claim language, and is instead done merely for the convenience of the Board.

VI. Grounds of Rejection to be Reviewed on Appeal

Whether Claims 1 and 11-15 are unpatentable under 35 U.S.C. § 103(a) over *Huston et al.* (U.S. Patent No. 3,407,027) in view of *Hennebert et al.* (U.S. Patent No. 4,764,351).

Whether Claims 2, 5, 6 and 19 are unpatentable under 35 U.S.C. § 103(a) over *Huston et al.* '027 in view of *Hennebert et al.* '351 and further in view of *Spence* (U.S. Patent No. 4,919,888).

VII. Argument

A. Prior Art Applied

i. *Huston et al.* (U.S. Patent No. 3,407,027)

The primary reference upon which the Examiner relies, *Huston et al.* (U.S. Patent No. 3,407,027), discloses an autoclave having a double walled construction. *Huston* discloses that the inner shell 14 and the fastening ring 25 may be made of a high quality corrosion resistant material while the outer shell 12 and the end ring 15 may be made of flange grade material which is lower in cost than the corrosion resistant material. Therefore, it is possible to make a structurally strong chamber

utilizing the low cost material for structural strength while the lining (inner shell 14) and fastening ring are made up of more expensive material. See column 2, lines 16-24. *Huston* further discloses that utilizing this structure makes it possible to make the inner shell 14 thinner and to space the inner shell 14 and the outer shell 12 apart to obtain the required strength without regard to the length of the arms 20 of the door 11. See column 2, lines 33-39.

As further disclosed by *Huston*, the outer shell 12 is connected to the inner shell 14 at the door end by the end ring 15. The fastening ring 25 is welded at 23 to the end ring 15 and is welded to the inner shell at 29. The end ring 15 is welded to the inner shell 14 at 27 and to the outer shell at 22. Thus, the outer shell 12 and the inner shell 14 are held in spaced relation by the stay bars 28.

ii. *Hennebert et al.* (U.S. Patent No. 4,764,351)

The sterilization apparatus by *Hennebert* relates to low temperature sterilization (see column 2, lines 3 and 12-15), specifically formaldehyde gas sterilization. The apparatus for sterilization comprises a treatment chamber 1 with constant temperature control 3, 4, 5 connected to a source of vacuum 6, 7, 8, 9, and to a circuit for admitting a carrier gas comprising a means 10 for sterilizing a gas and a means 14 for heating the gas at constant temperature as well as a steam generator 16 connected to a water supply 19 and to a system 20 for controlling the temperature and/or pressure 20.

Formaldehyde sterilization or ethylene oxide are used when objects to be sterilized cannot be subjected to "elevated temperatures in conventional heat sterilization methods." Col. 1, lines 14-23. Formaldehyde sterilisation (see column

1, line 33) or ethylene oxide (column 1, line 23) are used when the objects to be sterilised cannot be subjected to elevated temperatures in conventional heat sterilization methods, i.e. cannot be sterilized in an autoclave. (See column 1, lines 14-23, in which *Hennebert et al.* disclose that recourse to gaseous sterilisation is essential for sterilising articles which cannot be subjected to elevated temperatures.) The maintenance of a temperature of 60° C. in the whole apparatus avoids vapor pressures above atmospheric pressure and hence the safety accessories and measures required by autoclave and boilers, and enables the heat control circuits to be simplified. Col. 6, lines 37-41.

iii. *Spence* (U.S. Patent No. 4,919,888)

Referring to Figs. 1-3, *Spence* is directed to a sterilization container system 10 including a filter means in the base 12 and/or lid 14 which permits the entry and exit of sterilant into and out of sterilization container 10 while it is being sterilized, but which do not permit the entry of microorganisms into the sterilization container system 10. Col. 3, lines 34-42. Base 12 comprises a bottom wall 18; a pair of side walls 20, 21; and a pair of end walls 22, each having an outwardly projecting handle 24. Extending completely around the top of base 12 is an outwardly projecting rim 25 (see FIG. 3). Located in the top of rim 25 is a gasket channel 26 which extends completely around the top of base 12. Held in the bottom of gasket channel 26, as by a compression fit, is a gasket 28, which also extends completely around the top of base 12. Col 3, lines 50-59.

Base 12 and lid 14 may be made from any suitable strong, durable metal and/or plastic material which is not adversely affected by the sterilant or by the

sterilizing conditions, such as stainless steel; aluminum; or P-1404 Noryl or P-101 polycarbonate plastic made by the General Electric Co. located in Pittsburgh, Pa. Base 12 and lid 14 are each preferably molded or formed in one piece, although they could be formed from separate components which are then assembled together, such as by gluing or by welding, in such a manner that they will not leak. Col. 4, lines 30-40.

B. Claims 1 and 11-15

Claims 1 and 11-15 are argued as a group with respect to patentability in view of the final rejection.

Claim 1, the only independent claim, stands rejected as being unpatentable under 35 U.S.C. §103(a) over *Huston et al.* (U.S. Patent No. 3,407,027) in view of *Hennebert et al.* (U.S. Patent No. 4,764,351). Appellant submits that the Office has not established a *prima facie* case of obviousness and that this rejection must therefore be withdrawn.

MPEP § 2143 states: To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The combination of *Huston* and *Hennebert et al.* fails to establish a *prima facie* case of obviousness against claim 1 because there is no teaching, suggestion

or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references. Furthermore, even if the references were combined, such a combination would not include all the features of claim 1.

The Office Action on page 3, paragraph number 4, states that the outer shell 12, the end ring 15 and the end member 17 of *Huston* correspond to the housing of the autoclave device recited in claim 1. (See page 3, lines 4-5 of the December 14, 206 Office Action.) Appellants respectfully disagree.

The Office Action on page 3, paragraph number 4, states that the inner shell 14 of *Huston* corresponds to the sterilisation chamber recited in claim 1. (See page 3, lines 7, 10, 12, 13 and 15-16 of the Office Action.) Applicants respectfully disagree.

The Office Action states on page 4, lines 9-12 that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct Huston chamber out of polymeric material as taught by Hennebert since plastic is low in cost and does not conduct electricity." Applicants respectfully disagree.

Huston discloses that the inner shell 14 and the fastening ring 25 may be made of a high quality corrosion resistant material while the outer shell 12 and the end ring 15 may be made of flange grade material which is lower in cost than the corrosion resistant material. Therefore, it is possible to make a structurally strong chamber utilizing the low cost material for structural strength while the lining (inner shell 14) and fastening ring are made up of more expensive material. See column 2, lines 16-24. *Huston* further discloses that utilizing this structure makes it possible to

make the inner shell 14 thinner and to space the inner shell 14 and the outer shell 12 apart to obtain the required strength without regard to the length of the arms 20 of the door 11. See column 2, lines 33-39.

As further disclosed by *Huston*, the outer shell 12 is connected to the inner shell 14 at the door end by the end ring 15. The fastening ring 25 is welded at 23 to the end ring 15 and is welded to the inner shell at 29. The end ring 15 is welded to the inner shell 14 at 27 and to the outer shell at 22. The outer shell 12 and the inner shell 14 are held in spaced relation by the stay bars 28.

The inner shell 14 of *Huston* is clearly permanently attached to the outer shell 12 through the end ring 15 an the welds 22, 23, 27, 29. The inner shell 14 is not releasably fastened to the autoclave outer shell 12 and thus the inner shell 14 does not correspond to the sterilisation chamber of claim 1. The outer shell 12, the end ring 15 and the end member 17 of *Huston* therefore do not correspond to the housing of claim 1.

Furthermore, *Huston* states that to obtain the strength required for large wall areas and high pressures, the working skins (i.e. the inner and outer shells) may be spaced apart according to strength requirements to obtain the proper stress design. See column 1, lines 37-42. Thus, one of ordinary skill in the art would not regard the inner shell 14 as a self supported structure, as recited in claim 1. Moreover, due to the high pressure operating conditions of the autoclave of *Huston*, the outer shell 12 must be present.

As disclosed in the above-identified application, in traditional autoclaves, a large amount of energy is consumed for heating the material in the metal chamber for each autoclaving cycle and there is a risk of burning for the personnel using the

autoclave. See page 6, lines 5-14 of the instant application. As the autoclave of *Huston* is heated, the welds 22, 23, 27, 29 and the stay bars 28 etc will transfer the heat from the inner shell 14 to the outer shell 12. The time under which the inner shell 14 is heated and the high temperature will also cause natural convection via the gas/air present in the space between the inner and outer shells 12, 14 and between the inner shell 14 and end member 17.

Huston merely suggests a nickel clad inner shell 14 surrounded by a solid outer shell 12 of steel due to the heat and pressure conditions in the chamber. See column 1, lines 37-42. Thus, the autoclave of *Huston* is a traditional autoclave made of metal. Additionally, as nickel has a high heat conductibility (higher than steel), Huston actually teaches away from the present invention.

Although *Hennebert et al.* disclose that their treatment chamber 1 is made of plastic in certain limited conditions, one of ordinary skill in the art would not have been motivated to form the inner shell 14 of *Huston* of plastic material based upon this disclosure. More specifically, *Hennebert* requires that the sterilization chamber be used in formaldehyde gas sterilization. Formaldehyde sterilization or ethylene oxide are used when objects to be sterilized cannot be subjected to "elevated temperatures in conventional heat sterilization methods." Col. 1, lines 14-23. The sterilization apparatus by *Hennebert* relates to low temperature sterilization (see column 2, lines 3 and 12-15), specifically formaldehyde gas sterilization. Formaldehyde sterilisation (see column 1, line 33) or ethylene oxide (column 1, line 23) are used when the objects to be sterilised cannot be subjected to elevated temperatures in conventional heat sterilization methods, i.e. cannot be sterilized in an autoclave. (See column 1, lines 14-23, in which *Hennebert et al.* disclose that

recourse to gaseous sterilisation is essential for sterilising articles which cannot be subjected to elevated temperatures.) *Hennebert* clearly disclose that their treatment chamber 1 is not to be used for sterilisation carried out in an autoclave, i.e. under elevated temperatures, and therefore do not use the temperatures in combination with the pressures that are used in an autoclave. Hence, *Hennebert* specifically teaches away from the use of its plastic sterilization chamber in a conventional high temperature autoclave apparatus -- as taught by *Hutson*.

If modified as the Examiner suggests, if the sterilization chamber of *Huston* were constructed of the plastics material suggested in *Hennebert*, there is no teaching or suggestion that the chamber would be able to withstand the sterilization pressures to be exerted thereon. The Federal Circuit has held that if a "proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). As such, Applicants submit that there is no motivation to combine the teachings of *Hennebert* with the traditional autoclave of *Huston* to make the modification proposed by the Examiner.

Hennebert et al. further disclose, in column 5, lines 22-27, that the chamber that is of a plastic material is used under the requirement of subatmospheric pressure, and includes embedded electrical heating elements. Thus, Hennebert do not disclose the use of a plastic sterilisation chamber in an autoclave in any way. Briefly, autoclave sterilisation is a heat sterilisation wherein the temperature is at least 120°C, and preferably at least 134°C. If *Hennebert et al.* contemplated the use of a plastic chamber in an autoclave, there would be no need to include heating

elements as the chamber would be heated during the sterilisation process. In other words, if the plastic chamber were to be used in an autoclave, why would *Hennebert et al.* provide heating elements to heat the chamber?

Thus, *Hennebert* do not teach a plastic chamber that has natural heat isolating properties and may withstand high temperatures at all. Furthermore, *Hennebert et al.* only disclose the use of plastic for sub-atmospheric pressures. See, for example, claim 3 of *Hennebert et al.* Consequently, the plastic chamber of *Hennebert* does not have the same requirements as an autoclave chamber. See, for example, page 2, paragraph (6) of the Declaration Under 37C.F.R.§1.132, filed March 30, 2005.

As disclosed in the instant application, some of the advantages of the claimed invention include a cool exterior, less noise, lower consumption of energy, shorter processing time, achievement of dry goods quicker, reduced bacterial build up, and less condensation.

For at least the foregoing reasons, it is respectfully submitted that the combination of *Huston* and *Hennebert et al.* fails to present a *prima facie* case of obviousness.

C. Claims 2, 5, 6 and 19

Claims 2, 5, 6 and 19 are argued as a group with respect to patentability in view of the final rejection.

The Examiner refers to the following in *Spence* (col. 4, lines 30-33), asserting that the sterilization chamber "may be made of any suitable metal and/or plastic material which are not adversely affected by the sterilant or by the sterilization

conditions." Applicants respectfully traverse the Examiner's reasoning in substituting the plastic container of *Spence* for an ASME-certified sterilization pressure chamber (i.e., one that is verified with extensive FEM-analysis). Thus, it is not the same pressure conditions for a *Spence* container with filter means being equalized in a sterilization pressure chamber and a sterilization pressure chamber (ASME-certified). The *Spence* container is not suitable to be used as a pressure chamber (internally pressurized) in an autoclave device, especially not according to the ASME. For instance, the container has only a microorganism proof seal between the lid and the base and is not adapted to be internally pressurized.

For at least the foregoing reasons, it is respectfully submitted that the combination of *Huston*, *Hennebert et al.* and *Spence* fails to present a *prima facie* case of obviousness.

VIII. Claims Appendix

See attached Claims Appendix for a copy of the claims involved in the appeal.

IX. Evidence Appendix

See attached Evidence Appendix for copies of evidence relied upon by Appellant.

X. Related Proceedings Appendix

See attached Related Proceedings Appendix for copies of decisions identified in Section II, supra.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date June 12, 2007

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VIII. CLAIMS APPENDIX

The Appealed Claims

1. (Previously Presented) Sterilisation chamber for use in an autoclave device including a housing, pressure means, and display means, said sterilisation chamber comprising;

a front planar wall surface including a front opening for allowing access to said chamber, a rear planar wall surface, and a chamber body portion disposed therebetween, said sterilisation chamber being adapted to enclose goods to be sterilized during a sterilisation process,

wherein said sterilisation chamber is releasably fastened within the autoclave device by releasably connecting the front wall surface and the rear wall surface directly to the housing of the autoclave device, said sterilisation chamber comprising at least an inlet integrally formed with said chamber for releasable connection to a sterilant source from the autoclave device, wherein an interior of said sterilisation chamber is pressurized during the autoclave process so as to define a sealed pressure chamber,

and wherein said sterilisation chamber defines a self supported structure manufactured essentially from a polymeric material having natural heat isolating properties so as to reduce the risk of burning to a person touching the housing of the autoclave device.

2. (Original) Sterilisation chamber according to claim 1, wherein said chamber is manufactured from an injection-mouldable material.

3. (Previously Presented) Sterilisation chamber according to claim 2, wherein a reinforced material is included in said injection-mouldable material.

4. (Previously Presented) Sterilisation chamber according to claim 2, wherein a reinforcement material, such as a rowing weave material is arranged around said injection moulded material, forming an outer layer of said chamber.

5. (Previously Presented) Sterilisation chamber according to claim 2, wherein said injection-mouldable material essentially is a polyamide material.

6. (Original) Sterilisation chamber according to claim 1, wherein said chamber is manufactured from a composite material.

7. (Original) Sterilisation chamber according to claim 6, wherein said composite material comprises a carbon fibre rowing weave and a concatenating polymer material.

8. (Original) Sterilisation chamber according to claim 7, wherein said concatenating polymer material is an epoxy material.

9. (Original) Sterilisation chamber according to claim 6, wherein said composite material comprises a glass fibre rowing weave and a concatenating polymer material.

10. (Previously Presented) Sterilisation chamber according to claim 9, wherein said concatenating polymer material is selected from the group consisting of polyvinyl, isopolyester and orthopolyester material.

11. (Previously Presented) Sterilisation chamber according to claim 1, wherein said chamber is releasably mountable in said sterilisation device.

12. (Previously Presented) Sterilisation chamber according to claim 1, wherein said chamber is essentially manufactured in one continuous piece.

13. (Previously Presented) Sterilisation chamber according to claim 12, wherein components comprising at least one of inlets and outlets for steam, moisture and the like, are integrally formed with said chamber.

14. (Previously Presented) Sterilisation chamber according to claim 12, wherein said chamber is sealing closed by a movable sealing chamber door on the sterilization device.

15. (Previously Presented) Sterilisation device, being provided with a sterilisation chamber, in which a sterilisation process is intended to be performed, wherein said chamber is as described in claim 1.

16. (Previously Presented) Sterilisation chamber according to claim 3, wherein a reinforcement material, such as a rowing weave material is arranged around said injection moulded material, forming an outer layer of said chamber.

17. (Previously Presented) Sterilisation chamber according to claim 3, wherein said injection-mouldable material essentially is a polyamide material.

18. (Previously Presented) Sterilisation chamber according to claim 4, wherein said injection-mouldable material essentially is a polyamide material.

19. (Previously Presented) Sterilisation chamber according to claim 2, wherein said chamber is releasably mountable in said sterilisation device.

20. (Previously Presented) Sterilisation chamber according to claim 14, wherein said chamber is provided with a pair of integrally formed tracks, in which the sealing chamber door may be slidably mounted, wherein when said releasably fastened chamber is removed from the sterilization device said tracks are also removed therewith.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None